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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,147	01/10/2006	John Hawkins	MPD364	6121

7590 07/31/2008

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EXAMINER	
WANG, CHUN CHENG	
ART UNIT	PAPER NUMBER
4171	

MAIL DATE	DELIVERY MODE
07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,147	HAWKINS, JOHN	
	Examiner	Art Unit	
	Chun-Cheng Wang	4171	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27-30* is/are rejected.

7)☒ Claim(s) *1,2,17-21 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-25 and 27-30 are pending and claim 26 is canceled.

Claim Objections

2. Change "characterised in that" to "wherein" in claims 1, 2, 17-21 and 27.

3. Change "…graph of conductivity of against %..." to "…graph of conductivity against %..." in claim 2.

4. Change "A non-ionic structure surfactant system..." to "A structure surfactant system…" in claim 2, to make the term consistent.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term 'said hydrophobic groups' in the last 2 lines cause confusion, claim contains hydrophobic groups in the surfactants and one in acids and/or alcohols, it is not clear which hydrophobic groups having at least 30 wt.% of bent chain groups.

7. Claim 27: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where

broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 27 recites the broad recitation "from 0 to saturation of a water-soluble carbohydrate", and the claim also recites "from 25% by weight, based on the weight of the suspending system, to saturation of a dissolved carbohydrate structurant" which is the narrower statement of the range/limitation. The claim will be searched based on examiner's interpretation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4-15, 17, 21 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hawkins et al. (EP0414549 A2).

10. Claim 1: Applicants recite an aqueous based structured surfactant system, having solid-suspending properties and comprising: water; surfactants, said surfactants consisting essentially of non-ionic and/or zwitterionic surfactants, each comprising at least one hydrophobic group and a non-ionic or zwitterionic hydrophilic group; from 0 to 50%, based on the weight of surfactant, of acids and/or alcohols having a hydrophobic group and a carboxyl or hydroxyl group respectively; and from 0 to saturation of a water-soluble carbohydrate; said surfactant, acid, alcohol, and carbohydrate being present in proportions adapted to form a pourable structured suspending system; characterised in that at least 30% by weight of said hydrophobic groups are bent chain groups.

Hawkins et al. '4549 discloses a structured surfactant system comprising: water; a surfactant or mixture of surfactants present in a concentration sufficient to form a spherulitic or dispersed lamellar phase in the absence of electrolyte; and a substantially insoluble functional material, suspended in the composition (Abstract). (Surfactants) particularly preferred are nonionic and mixed nonionic surfactants (page 5, line 34), surfactant may comprise an amine oxide or alkylated amine oxide or an amphoteric surfactant such as a betaine or sulphobetaine (page 5, lines 51-52), surfactants in the presence of cosurfactants which may then be used to form spherulitic compositions. Such compounds are amphiphiles having a hydrophobic group such as an alkyl, alkenyl or alkaryl group comprising 6 to 22 aliphatic carbon atoms and a polar group such as a hydroxyl, carboxyl, carbonyl, ester, amino, benzylamino, alkylamino, pyridine, amido, nitro, cyano or halo group. Typical examples are fatty alcohols such as octyl, lauryl, cetyl or stearyl alcohol, fatty acids such as decanoic, lauric, stearic, coconut, palmitic or behenic acids, unsaturated acids such as oleic, linoleic or linolenic acids, phenols such as nonyl phenol, halides such as p-chloro-dodecyl benzene, ketones such as dodecyl cyclohexanone, aldehydes such as octanal, amines such as coconut fatty amine, dodecyl dimethylamine, glycerides such as olive oil or glyceryl distearate and heterocyclics such as clauryl pyridine. (page 6, lines 5-16). Hawkins also disclose a pourable automatic dishwashing composition (structured surfactant system) comprising 6.6 wt% Lauric acid 9 mole ethoxylated and 13.3 wt % cetyl/oleyl alcohol 6 mole ethoxylated, i.e. 33.2 wt% of surfactant and 66.8 wt% (13.3/(13.3+6.6) * 100%) of bent chain group by the total weight of the surfactant and alcohol (page 6, Example 1).

11. Claim 4: Applicants further recite wherein the hydrophobic groups are aliphatic hydrocarbon groups having more than 10, but less than 30, carbon atoms.

Hawkins et al. '4549 discloses amphiphiles having a hydrophobic group such as an alkyl, alkenyl or alkaryl group comprising 6 to 22 aliphatic carbon atoms and a polar group such as a hydroxyl, carboxyl, carbonyl, ester, amino, benzylamino, alkylamino, pyridine, amido, nitro, cyano or halo group. Typical examples are fatty alcohols such as octyl, lauryl, cetyl or stearyl alcohol, fatty acids such as decanoic, lauric, stearic, coconut, palmitic or behenic acids, unsaturated acids such as oleic, linoleic or linolenic acids, phenols such as nonyl phenol, halides such as p-chloro-dodecyl benzene, ketones such as dodecyl cyclohexanone, aldehydes such as octanal, amines such as coconut fatty amine, dodecyl dimethylamine, glycerides such as olive oil or glyceryl distearate and heterocyclics such as clauryl pyridine. (page 6, lines 5-16).

12. Claims 5 and 6: Applicants further recite wherein the proportion of bent chain hydrophobic groups is greater than 40% (claim 5); and is greater than 75% (claim 6).

Hawkins et al. '4549 discloses 82.5 wt% of bent chain hydrophobic groups, {6.6/(6.6+1.4) * 100%} (page 7, Example 2).

13. Claim 7: Applicants further recite wherein the bent chain groups are selected from oleyl, erucyl, palmitoleyl, nervonyl and isostearyl.

Hawkins et al. '4549 discloses unsaturated acids such as oleic, linoleic or linolenic acids and nonyl phenol as bent chain groups (page 6, lines 12-13).

14. Claim 8: Applicants further recite wherein the total proportion of surfactant is between 2 and 35%.

Hawkins et al. '4549 discloses a pourable automatic dishwashing composition (structured surfactant system) comprising 6.6 wt% Lauric acid 9 mole ethoxylated and 13.3 wt % cetyl/oleyl alcohol 6 mole ethoxylated, i.e. 33.2 wt% of surfactant and 66.8 wt% (13.3/(13.3+6.6) * 100%) of bent chain group by the total weight of the surfactant and alcohol (page 6, Example 1). A typical range of concentrations of the surfactants is from 7 to 50% (Page 5, line 30).

15. Claim 9: Applicants further recite wherein the non-ionic surfactants are selected from polyglyceryl fatty esters, fatty acid ethoxylates, fatty acid monoalkanolamides, fatty acid dialkanolamides, fatty acid alkanolamide ethoxylates, propylene glycol monoesters, fatty alcohol propoxylates, alcohol ethoxylates, alkyl phenol ethoxylates, fatty amine alkoxylates and fatty acid glyceryl ester ethoxylates.

Hawkins et al. '4549 discloses nonionic and mixed nonionic surfactants, which are mixtures of fatty alcohol ethoxylates and mixtures of fatty alcohol ethoxylates with fatty acid ethoxylates or mixed ethoxylated/propoxylated alcohols and fatty acids ethoxylates. For example mixtures comprising one or more C_{10} to C_{20} average fatty alcohols and or fatty acids alkoxylated with from 5 to 15 ethyleneoxy and/or propyleneoxy groups, are especially useful. Other non-ionic surfactants which may be used include alkoxylated alkylphenols, alkoxyated amines, alkoxylated sorbitan or glycerol esters of fatty acids, and alkanolamides such as coconut mono-di-or tri-ethanolamide and mixtures thereof.

16. Claims 10 and 11: Applicants further recite wherein the surfactants have a mean HLB greater than 6.5 (claim 10); and wherein the surfactants have a mean HLB greater than 9 (claim 11).

Hawkins et al. '4549 discloses mixture of surfactants have a mean HLB between 10 and 13 (page 5, line 9).

17. Claim 12: Applicants further recite wherein the surfactant comprises a mixture of at least one relatively high HLB surfactant with at least one relatively low HLB surfactant.

Hawkins et al. '4549 discloses mixture of surfactants comprises at least one surfactant with a solubility parameter greater than 13 and at least one surfactant with a solubility parameter below 10 (page 5, lines 7-8).

18. Claims 13 and 14: Applicants further recite wherein the high HLB surfactant has an HLB greater than 10 (claim 13); and wherein the high HLB surfactant has an HLB greater than 14.5 (claim 14).

Hawkins et al. '4549 discloses surfactant comprises at least one surfactant with solubility parameter greater than 13 (page 5, lines 8-9).

19. Claim 15: Applicants further recite wherein the low HLB surfactant has an HLB less than 8.

Hawkins et al. '4549 discloses surfactant comprises at least one surfactant with solubility parameter below 10 (page 5, line 9), which cover all the range of the instant claim.

20. Claim 17: Applicants further recite wherein zwitterionic surfactants are present in a proportion less than 70%, by weight of the total surfactant.

Hawkins et al. '4549 discloses amphiphile, compounds which on account of their low solubility in water are not usually effective as surfactants and are not usually classified as such but which are useful surfactants in the presence of cosurfactants which may then be used to form spherulitic compositions, is less than 1% by weight soluble in water, e.g. less than 0.5% especially less than 0.2%, e.g. less than 0.1%. Hawkins also discloses a typical range of concentrations of the surfactants is from 7 to 50% more usually 10 to 40% preferably 15 to 30%. The amphiphile, which reads on zwitterionic surfactant, concentration is less than 14.3 % by the weight of total surfactant.

21. Claim 21: Applicants further recite wherein it contains an electrolyte, in concentrations of 0 to 4%, by weight.

Hawkins et al. '4549 discloses the composition being substantially free from electrolyte (page 5, line 6). Hawkins also defines "substantially free from electrolyte" means containing insufficient electrolyte to destabilize the suspension. Typically this implies compositions containing less than 0.5%, preferably less than 0.2% e.g. less than 0.1% by weight, based on the weight of the composition, of electrolytes added as such, other than any "tramp" electrolyte unavoidably present in the surfactant, or in the suspended Functional Material or any dissolved portion of the suspended solid (page 2, lines 31-35).

22. Claims 24 and 25 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hawkins et al., (EP0414549 A2).

23. Claims 24 and 25: Applicants recite a method of suspending pharmaceutical or veterinary active ingredients comprising: providing a structured surfactant system, having solid-suspending properties and comprising: water; surfactants, said surfactants consisting essentially of non-ionic and/or zwitterionic surfactants, each comprising at least one hydrophobic group and a non-ionic or zwitterionic hydrophilic group; from 0 to 50%, based on the weight of surfactant, of acids and/or alcohols having a hydrophobic group and a carboxyl or hydroxyl group respectively; and from 0 to saturation of a water-soluble carbohydrate; said surfactant, acid, alcohol, and carbohydrate being present in proportions adapted to form a pourable structured suspending system; characterised in that at least 30% by weight of said hydrophobic groups are bent chain groups; providing a pharmaceutical or veterinary active ingredient; and contacting the structured surfactant system and the pharmaceutical or veterinary active ingredient (claim 24) and a suspension formed by the method of claim 24 (claim 25).

24. Hawkins et al. '4549 disclose a structured surfactant system comprising: water; a surfactant or mixture of surfactants present in a concentration sufficient to form a spherulitic or dispersed lamellar phase in the absence of electrolyte; and a substantially insoluble functional material, suspended in the composition (Abstract). (Surfactants) particularly preferred are nonionic and mixed nonionic surfactants (page 5, line 34), surfactant may comprise an amine oxide or alkylated amine oxide or an amphoteric surfactant such as a betaine or sulphobetaine (page 5, lines 51-52), surfactants in the presence of cosurfactants which may then be used to form spherulitic compositions. Such compounds are amphiphiles having a hydrophobic group such as an alkyl, alkenyl or alkaryl group comprising 6 to 22 aliphatic carbon atoms and a polar group such as a hydroxyl, carboxyl, carbonyl, ester, amino, benzylamino, alkylamino, pyridine, amido, nitro, cyano or halo group. Typical examples are fatty alcohols such as octyl, lauryl, cetyl or stearyl alcohol, fatty acids such as decanoic, lauric, stearic, coconut, palmitic or behenic acids, unsaturated acids such as oleic, linoleic or linolenic acids, phenols such as nonyl phenol, halides such as p-chloro-dodecyl benzene, ketones such as dodecyl cyclohexanone, aldehydes such as octanal, amines such as coconut fatty amine, dodecyl dimethylamine, glycerides such as olive oil

or glyceryl distearate and heterocyclics such as clauryl pyridine. (page 6, lines 5-16). Hawkins also disclose a pourable automatic dishwashing composition (structured surfactant system) comprising 6.6 wt% Lauric acid 9 mole ethoxylated and 13.3 wt % cetyl/oleyl alcohol 6 mole ethoxylated, i.e. 33.2 wt% of surfactant and 66.8 wt% (13.3/(13.3+6.6) * 100%) of bent chain group by the total weight of the surfactant and alcohol (page 6, Example 1). Hawkins et al. '4549 also disclose the suspended material may, for example, comprise a water insoluble detergent builder such as a zeolite or a particulate ion exchange resin, an inert abrasive such as calcite, talc or a substantially water insoluble pesticide, catalyst, ceramic, pharmaceutical or pigment or a silicone oil, or substantially water insoluble gas (page 6, lines 22-25). The pharmaceutical ingredient must necessary be mixed with the surfactant system to obtain a pharmaceutical suspension. A pharmaceutical suspension is formed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 2 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (EP0414549 A2).

26. Claim 2: Applicant recite a structured surfactant system according to claim 1 characterised in that the proportion of hydrophobic groups, which are bent chain, is greater than that corresponding to the maximum or turning point value in the graph of conductivity of against % bent chain groups.

27. Hawkins et al. '4549 is silent on the graph of conductivity vs. 5 chain groups and the relation between the hydrophobic groups and the graph.

However, the conductivity of the surfactant system increase due to the increase of charged group or charge transfer groups, and then decrease in conductivity due to the number of hydrophobic groups that entangle or the formation of micelles which lower the mobility of the charge group, which may tend to stabilize the system. Different surfactant system has its own conductivity behaviors. The caselaw has held that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to do routine experimentation to determination the concentration of the hydrophobic groups that has maximum conductivity and then apply the hydrophobic group concentration necessary to stabilize the surfactant system.

28. Claim 23: Applicant further recite a structured surfactant system according to claim 1 further comprising suspended particles of at least one pharmacological or veterinary active substance, said particles comprising at least two populations differentiated with respect to size and including a first population, of non-colloidal particles comprising at least 10% based on the total weight of the particles, and a second population of particles comprising at least 10%, based on the total weight of the particles,

wherein said first population has a mean particle size at least ten times the mean particle size of said second population.

Hawkins et al. '4549 disclose the suspended material may comprise substantially water insoluble pharmaceutical and typically particles of from1 to 100 microns may be suspended (page 6, lines 22-26). Hawkins et al. '4549 is silent on the particle size distribution. Particle size and crystal form of the pharmaceuticals affects dissolution. **Smaller size particles dissolve at faster rate, but which is not always ideal. Larger size particles dissolve at a slower rate, which may prolong the duration of action.** One could have a small particle size in small proportion to deliver enough initial dosage, increasing the size of the particles to have extended period of action. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to perform routine experiments to vary the particle size distribution for different pharmaceuticals/surfactants combination, desired dosage and duration to obtain the claimed particle size distribution. The case law held that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

29. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins et al. (EP0414549 A2) in view of Hawkins, (WO/2001/005932, published 01/25/2001), US 2004/0235702 A1 is used as a translation.

The disclosure of Hawkins et al. '4549 is adequately set forth above and is incorporated herein by reference.

30. Applicant recite a structured surfactant system according to claim 1, which is an expanded Lα-phase, and which comprises water, a dissolved carbohydrate, and a non-ionic surfactant characterised by a small angle X-ray diffraction peak corresponding to a d-spacing greater than 50 nm.

Hawkins et al. '4549 disclose the structured surfactant system typically has a repeat spacing of 110 nm to 150 nm between bilayer shells (page 6, lines 36-37). Hawkins et al. '4549 is silent on the dissolved carbohydrate.

Hawkins '5702 disclose a structured surfactant system having suspending properties which comprises a surfactant, water and a structurant, characterised in that said structurant comprises a water soluble carbohydrate. The structured system may typically be a very highly expanded G-phase, e.g. one having a lamellar repeat spacing greater than 8 and usually greater than 155 nm. The composition, in the absence of suspended matter, is preferably clear and transparent [0032]. There is a need for a system which contains high levels of surfactant but which does not require expensive deflocculants. There is a need for a system that contains relatively soluble surfactants but which does not require the presence of electrolyte as a structurant [0029]. Hawkins '5702 also disclose some or all of the above needs, may be obtained by using water soluble carbohydrate to impart structure to the surfactant system, instead of or in addition to the electrolytes used [0030]. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to include water soluble carbohydrate to impart structure to the surfactant system without using expensive deflocculants to fulfill the needs and obtain the claimed structured surfactant system.

31. Claims 16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (EP0414549 A2) in view of Hawkins, (WO/2001/005932, published 01/25/2001), US 2004/0235702 A1 is used as a translation.

32. Claim 16: Applicant further recite wherein the mixture has a weight ratio of low HLB surfactant to high HLB surfactant of less than 2:1, but more than 1:10.

Hawkins et al. '4549 is silent on the weight ratio of the low HLB surfactant to high HLB surfactant.

Hawkins '5702 disclose 2.5% coconut diethanolamide mixed with 10 % sodium C_{12-14} alkyl (3 mole ethoxy sulphate) to form a surfactant system, which has a 1:4 weight ratio of low HLB surfactant to high HLB surfactant (page 8, Example 14).

33. Claims 19 and 20: Applicant further recite a structured surfactant system according to claim 1, characterised in that it contains a carbohydrate, which is a mono or disaccharide sugar (claim 19); and a structured surfactant system according to claim 1, characterised in that the carbohydrate is present in a concentration between 15% and 75%, by weight (claim 20).

Hawkins '5702 disclose preferred carbohydrates are mono- and di- saccharide sugars such as sucrose, glucose or fructose. Hawkins '5702 also disclose in the absence of electrolyte, the carbohydrate is present in a proportion of at least 25% e.g. at least 30% and usually more than 40% by weight [0042].

34. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (EP0414549 A2) in view of Heertje et al., (US 6368652 B1).

35. Claim 18: Applicant further recites wherein the zwitterionic surfactant is lecithin.

Hawkins et al. '4549 is silent on the surfactant lecithin.

36. Heertje et al. disclose formation of mesomorphic phases of edible surfactant molecules and water can give rise to a firm texture and consistency. The use of this property of mesomorphic phases, to give consistency to products, is new to the food business. However, it should be noted that this use may already be known in other areas such as cosmetics and pharmaceuticals (column 1, lines 46-52). The term mesomorphic phase is intended to include all

semi-ordered phases of water and edible surfactant materials. Examples of mesomorphic phases are cubic, hexagonal, alpha crystalline gel, beta-crystalline coagel and lamellar phases. Preferred mesomorphic phases are lyotropic phases; also preferred are lamellar phases. Term lamellar phase refers to any system having a pattern of alternating bilayers of edible surfactants and water. Examples of lamellar phases are lamellar droplet phases, lamellar gel phases and lamellar phases containing extended parallel layers of surfactants and water (column 1, lines 53-67). In the lamellar phase surfactants, are believed to form a bilayer structure. It is believed that a bulk lamellar phase consists of stacks of bi-layer structures with an intervening aqueous phase. Products comprise bulk regions of the lamellar phase whereas it has been suggested that known products of the prior art might contain boundary layers of this phase at interfaces, such as those found around oil-droplets in water-continuous fatty products (, and column 2, lines 1-8). Heertje et al. also disclose the use of mesomorphic phases of edible surfactants as structuring agent (column 2, lines 57-58) and lecithin is the preferred (edible) cosurfactants (column 10, lines 37-38). It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to utilize the teaching from Heertje et al. using lecithin or other edible surfactant in the structured surfactant system to give consistency to food products desired.

37. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins et al. (EP0414549 A2) in view of Huet et al., (US 6426333 B1).

38. Claim 22: Applicants further recite structured surfactant system according to claim 1, comprising a water insoluble pharmaceutical or veterinary active ingredients, which consists essentially of water; from 0% to saturation of a dissolved carbohydrate; from 0 to 10% by weight, based on the weight of the suspending system, of electrolyte; and from 3 to 10% by weight, based on the weight of the suspending system, of a surfactant mixture consisting of (A) a pharmacologically or veterinarily acceptable surfactant, having an HLB greater than 10, and (B) a pharmacologically or veterinarily acceptable

surfactant, with a HLB less than 10, oleic acid or a phospholipid in a weight ratio of from 10:1 to 1:1, (A):(B).

Hawkins et al. '4549 disclose the structured surfactant system which the suspended material may comprise substantially water insoluble pharmaceutical (page 6, lines 23-24). The surfactant system comprises water, substantially water insoluble pharmaceutical, 0 % carbohydrate, and substantially free from electrolytes (Abstract), less than 0.5 % ((page 2, line 32). Some surfactants, i.e. nonionic and amphiphiles surfactants, form stable spherulitic structures at concentrations in the range of 4 to 20 % (page 6, line 34); the amphiphile is less than 1 % (page 6, line 14). Hawkins et al. also disclose oleic acid as one of amphiphiles (page 6, line 12). The weight ratio of nonionic surfactant, i.e. HLB > 10 in the invention, to amphiphiles surfactant, i.e. HLB < 10, is 4:1 to 20:1.

Huet et al. disclose suitable surfactants for spot-on compositions for the treatment or prophylaxis of parasite infestations in mammals or birds, anionic surfactants, such as alkaline stearates, in particular sodium, potassium or ammonium stearate; calcium stearate or triethanolamine stearate; sodium abietate; alkyl sulphates, in particular sodium lauryl sulphate and sodium cetyl sulphate; sodium dodecylbenzenesulphonate or sodium dioctyl sulphosuccinate; or fatty acids, in particular those derived from coconut oil, cationic surfactants, such as water-soluble quaternary ammonium salts of formula $N^+R'R''R'''R''''Y^-$, in which the R radicals are identical or different optionally hydroxylated hydrocarbon radicals and Y^- is an anion of a strong acid, such as halide, sulphate and sulphonate anions; cetyltrimethylammonium bromide is one of the cationic surfactants which can be used, amine salts of formula $N^+R'R''R'''$, in which the R radicals are identical or different optionally hydroxylated hydrocarbon radicals; octadecylamine hydrochloride is one of the cationic surfactants which can be used, non-ionic

surfactants, such as optionally polyoxyethylenated esters of sorbitan, in particular Polysorbate 80, or polyoxyethylenated alkyl ethers; polyethylene glycol stearate, polyoxyethylenated derivatives of castor oil, polyglycerol esters, polyoxyethylenated fatty alcohols, polyoxyethylenated fatty acids or copolymers of ethylene oxide and of propylene oxide, amphoteric surfactants, such as substituted lauryl compounds of betaine, or preferably a mixture of at least two of the compounds listed (column 12, lines 17-45). Different surfactants will affect differently with pharmaceuticals. It would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to select the surfactant(s) Huet et al. suggested and perform routine experiments of the composition and surfactant weight ratio to obtain the claimed composition. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

39. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (EP0414549 A2) in view of Heertje et al., (US 6368652 B1).

40. Claim 27: Applicant recites a food product or beverage comprising a continuous aqueous liquid phase, and suspended, non-colloidal solid, characterised in that said aqueous phase is a structured

surfactant system having solid-suspending properties and comprising: water; surfactants, said surfactants consisting essentially of non-ionic and/or zwitterionic surfactants, each comprising at least one hydrophobic group and a non-ionic or zwitterionic hydrophilic group; from 0 to 50%, based on the weight of surfactant, of acids and/or alcohols having a hydrophobic group and a carboxyl or hydroxyl group respectively; and from 0 to saturation of a water-soluble carbohydrate; said surfactant, acid, alcohol, and carbohydrate being present in proportions adapted to form a pourable structured suspending system; characterised in that at least 30% by weight of said hydrophobic groups are bent chain groups, which consists essentially of water; from 25% by weight, based on the weight of the suspending system, to saturation of a dissolved carbohydrate structurant; from 0 to 10% by weight, based on the weight of the suspending system, of electrolyte; and from 3 to 10% by weight, based on the weight of the suspending system, of a surfactant mixture consisting of (A) an edible surfactant, having an HLB greater than 10, (B) an edible surfactant, with a pH less than 10, in a weight ratio of from 10:1 to 1:1, (A):(B).

Hawkins '4519 discloses a structured surfactant system comprising: water; a surfactant or mixture of surfactants present in a concentration sufficient to form a spherulitic or dispersed lamellar phase in the absence of electrolyte; and a substantially insoluble functional material, suspended in the composition (Abstract). (Surfactants) particularly preferred are nonionic and mixed nonionic surfactants (page 5, line 34), surfactant may comprise an amine oxide or alkylated amine oxide or an amphoteric surfactant such as a betaine or sulphobetaine (page 5, lines 51-52), surfactants in the presence of cosurfactants which may then be used to form spherulitic compositions. Such compounds are amphiphiles having a hydrophobic group such as an alkyl, alkenyl or alkaryl group comprising 6 to 22 aliphatic carbon atoms and a polar group such as a hydroxyl, carboxyl, carbonyl, ester, amino, benzylamino, alkylamino, pyridine, amido, nitro, cyano or halo group. Typical examples are fatty alcohols such as octyl, lauryl, cetyl or stearyl alcohol, fatty acids such as decanoic, lauric, stearic, coconut, palmitic or behenic acids, unsaturated acids such as oleic, linoleic or linolenic acids, phenols such as nonyl phenol, halides such as p-chloro-dodecyl benzene, ketones such as dodecyl cyclohexanone, aldehydes such as octanal, amines such as coconut fatty amine, dodecyl dimethylamine, glycerides such as olive oil or glyceryl distearate and heterocyclics such as clauryl pyridine (page 6, lines 5-16). Hawkins

also disclose a pourable automatic dishwashing composition (structured surfactant system) comprising 6.6 wt% Lauric acid 9 mole ethoxylated and 13.3 wt % cetyl/oleyl alcohol 6 mole ethoxylated, i.e. 33.2 wt% of surfactant and 66.8 wt% (13.3/(13.3+6.6) * 100%) of bent chain group by the total weight of the surfactant and alcohol (page 6, Example 1).

Hawkins '4519 is silent on carbohydrate, edible surfactants and the weight ratio of the edible surfactants.

Heertje et al. disclose formation of mesomorphic, i.e. structured, phases of edible surfactant molecules and water can give rise to a firm texture and consistency. The use of this property of mesomorphic phases, to give **consistency** to products, is new to the food business. However, it should be noted that this use may already be known in other areas such as cosmetics and pharmaceuticals (column 1, lines 46-52). Heertje et al. also disclose a low calorie pourable dressing was made using the following ingredients: (1) gel phase 33.5% (mixture of 3.5% Monoglyceride (Hymono 8803), i.e. non-ionic surfactant HLB>10, i.e. non-ionic surfactant, 0.14% Datem, i.e. diacetyl tartaric ester of monoglycerides an pH <10 anionic surfactant, and the balance being water), and (2) water phase: water 31%, sugar 15%, i.e. carbohydrate,, salt, i.e. electrolyte, 1.4%, cider vinegar (5% acetic acid), 13% tomato paste, 3% (ex Del Monte, double concentrated) flavors, 1.5% biopolymeric thickeners, 0.5% potassium sorbate, and 0.1% sun flower seed oil 1% (column 15, Example I.2). Cider vinegar (acetic acid) could be used to adjust the pH value. Heertje et al. disclose dressings are in general low pH products with a preferred pH of from 2-6, more preferred 3-5, for example about 3.5. The use of ionic surfactants is at these pH values is limited to a number of compounds, because proper functioning of the ionic surfactant requires that the surfactant molecule is at least partly dissociated at the indicated pH.

(column 8, lines 25-30). The presence of "non-ionic", "cationic" and "anionic" surfactants is of course dependent on the pH-value of the foodstuff in which the surfactants are used (column 6, lines 23-24). The combination of non-ionic and ionic surfactants is preferred because the **ionic surfactants are believed to give rise to an electrical charge at the interface of the mesomorphic structure** used (column 6, lines 30-33) and the nonionic surfactant and the ionic surfactant are used in **weight ratios of from 100:1 to 1:10**, more preferred 50:1 to 1:1, for example 40:1 to 10:1 (column 6, lines 39-42). The caselaw has held that "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to adjust the concentration of edible nonionic surfactant, which has HLB > 10, and ionic surfactant, which has pH < 10 and could adjust pH of the desired foodstuffs, and optimize the composition to obtain the claimed weight ratio to give consistency to food products.

41. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins et al. (EP0414549 A2) in view of Huet et al. (US 6426333 B1) and Sangekar et al. (US 3957662).

42. Applicants recite A structured surfactant system of claim 1 further comprising an alkaline earth metal soap (claim 28), wherein the alkaline earth metal soap is calcium stearate (claim 29), and the alkaline earth metal soap is present in an amount greater than 20%, but less than 48% by weight based on the weight of the structured surfactant system (claim 30).

Hawkins et al. '4549 include soaps as one of anionic surfactants of particular value (page 5, line 45). Hawkins et al. '4549 is silent on the alkaline earth metal soap, calcium stearate, is present in an amount greater than 20%, but less than 48% by weight based on the weight of the structured surfactant system.

Huet et al. disclose crystallization inhibitors which can be used in the composition include anionic surfactants, such as alkaline stearates, in particular sodium, potassium or ammonium stearate; calcium stearate or triethanolamine stearate (column 12, lines 17-19). Huet et al. also disclose cosurfactant to surfactant ratio will preferably be from about 1/7 to about 1/2. There will preferably be from about 25 to about 75% V/V of surfactant and from about 10 to about 55% V/V of cosurfactant in the microemulsion (column 11, lines 49-52). Sangekar et al. disclose improved pharmaceutical lubricants comprising finely divided magnesium or calcium stearate coated with a surfactant. The improved lubricants **greatly enhance disintegration and dissolution time** of tablets and capsules prepared therefrom without loss in essential pharmaceutical lubricant properties (Abstract). The surfactant utilized to coat magnesium and calcium stearates in accordance with the present invention can be selected from the many commercially available surfactants of the anionic or non-ionic types (column 2, lines 35-40). The caselaw has held that "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to adjust the concentration of calcium stearate, as ionic surfactant or as lubricant, for the desired applicants, and optimize the composition to obtain the claimed amount of greater than 20%, but less than 48% by weight based on the weight of the structured surfactant system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun-Cheng Wang whose telephone number is (571)270-5459. The examiner can normally be reached on Monday to Friday w/alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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